From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To: DENISE M. SEREWICZ
BAXTER HEALTHCARE CORPORATION
ROUTE 120 & WILSON ROAD
ROUND LAKE IL 60073

RECEIVED
AUG 0 1 2000
FENWAL/PATENT LAW

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing *(day/month/year)*	27 JUL 2000
Applicant's or agent's file reference: F-5366	REPLY DUE: within TWO months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/14471	25 JUNE 1999	08 JULY 1998

International Patent Classification (IPC) or both national classification and IPC
IPC(7): B01D 39/00; B05D 5/00 and US Cl.: 210/490, 502.1, 507; 427/243

Applicant
BAXTER INTERNATIONAL INC.

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I [X] Basis of the opinion
- II [ ] Priority
- III [ ] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV [X] Lack of unity of invention
- V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI [ ] Certain documents cited
- VII [ ] Certain defects in the international application
- VIII [X] Certain observations on the international application

CASE F8-5366 PCT
DKT. DATE 9-27-00 SEEN BY ATTY. DM
FINAL DATE 9-27-00 RESP. SENT
SUBJECT Resp. to Written Opinion

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension., see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 08 NOVEMBER 2000

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	RICHARD W. WARD DEBORAH THOMAS PARALEGAL SPECIALIST
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0536

Form PCT/IPEA/408 (cover sheet) (July 1998)★

I. Basis of the opinion

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:

pages 1-34 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the claims:

pages 35-39 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the drawings:

pages 1-14 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the sequence listing part of the description:

pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE
[X] the claims, Nos. NONE
[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- [ ] restricted the claims. (See Supplemental Sheet)
- [X] paid additional fees.
- [ ] paid additional fees under protest.
- [ ] neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1 not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- [X] all parts.
- [ ] the parts relating to claims Nos. .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	23, 25-26, 28, 34-35	YES
	Claims	1-22, 24, 27, 29-33 and 36-39	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-39	NO
Industrial Applicability (IA)	Claims	1-39	YES
	Claims	NONE	NO

2. citations and explanations

Claims 1-22, 24, 27, 29-33 and 36-39 lack novelty under PCT Article 33(2) as being anticipated by the patent to SUGIYAMA et al (US 4,728,432). SUGIYAMA et al [432] discloses a composite membrane comprising particulates, a polymeric matrix, and a skin layer (see column 3, lines 29-56; "skin" or surfaces are formed when "prepared by a known method of producing porous membranes"), as recited in instant claim 1, and a method of making said membrane by providing a support (column 2, lines 50-51) and coating both sides of said support with a uniform thickness of a polymeric/particulate blend (see column 5), as recited in instant claim 12. SUGIYAMA et al [432] also discloses hydrophobic polyurethane (column 3, line 47), as recited in instant claims 2-3 and 13-14; more particles in an interior than in a "skin" surface (see above), as recited in instant claim 4 and 15; 70 % particulate and 30 % polymer (column 3, line 53), as recited in instant claims 5-6 and 16-17; rippled polyester mesh supports (column 3, lines 14-28), as recited in instant claims 7-8; a non-fiberized matrix (column 3), as recited in instant claim 9; a 400 micron thickness (column 3, line 59), as recited in instant claims 10-11 and 39; tetrahydrofuran (column 5, lines 6-7), as recited in instant claim 18; immersing in a non-solvent (column 5, line 14), as recited in instant claim 19; flowcasting or dipping methods, which are well known to involve movement of a substrate (column 3, line 35), as recited in instant claim 20; multiple dipping steps (column 5, lines 14-19), as recited in instant claim 21; drying (i.e., removal from a water bath, column 5), as recited in instant claim 22; treating with a 0.9% sodium chloride containing solution (i.e., blood, see abstract) as recited in instant claims 24, 27, and 29; a dipping method (column 3, line 35), as recited in instant claim 30; "superposing" into multiple layers (i.e., pleating or rippling, see column 4, line 13), as recited in instant claims 31-32; 10 micron carbon particles (see claim 3), as recited in instant claim 33; edge sealing a membrane of desired size (column 4, line 29-45), as recited in instant claim 36; 10 micron particles (see claim 3), as recited in instant claim 37; and a contoured, non-fiberized membrane (column 3 and figure 2), as recited in instant claim 38. See TAFT (US 4,011,871), column 5, lines (Continued on Supplemental Sheet.)

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 13 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): the use of the compound "polyurethene" is inconsistent with the disclosure and claim 2, as only a disclosure of "polyurethane" is provided in the instant specification.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

IV. LACK OF UNITY OF INVENTION:

1. This response is made to a telephone Lack of Unity requirement (see telephone memorandum attached hereto or attached to a prior Written Opinion).

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
40-47, for information relating to the salt content of blood.

Claims 23, 25, 28 and 35 lack an inventive step under PCT Article 33(3) as being obvious over SUGIYAMA et al [432], as applied to claim 12 or 24 above, and further in view of NAKASHIMA et al (US 4,384,954). Claim 25 recites the additional limitation of polyvinyl alcohol treatment. Claims 23 and 28 recite the additional limitation of drying. NAKASHIMA et al [954] teaches polyvinyl alcohol treatment (column 3, line 63) and drying (column 4, line 62). It would have been well within the skill of the routineer of the art to utilize the treatment or drying methods of NAKASHIMA et al [954] in conjunction with the process of SUGIYAMA et al [432] for the purpose of achieving a desired degree of hydrophilicity for a particular sorption process.

Claims 26 and 35 lack an inventive step under PCT Article 33(3) as being obvious over SUGIYAMA et al [432], as applied to claim 12 or 24 above, and further in view of HANCOCK et al (US 5,700,902). Claim 26 recites the additional limitation of glycerol treatment. Claim 35 recites the additional limitation of a copolymeric material. HANCOCK et al [902] teaches the use of polysulfone/PEO block copolymers treated with glycerol (column 15) for the use in artificial organs (column 5, lines 3-4). It would have been well within the skill of the routineer of the art to utilize the treated copolymer of HANCOCK et al [902] in place of the polysulfone of SUGIYAMA et al [432] for the purpose of improving membrane hydrophilicity (column 15).

Claim 34 lacks an inventive step under PCT Article 33(3) as being obvious over SUGIYAMA et al [432], as applied to claim 12 above, and further in view of GUNNING (US 3,908,044). Claim 34 recites limitations relating to continuous membrane production. SUGIYAMA et al [432] suggests a dipping method (column 3, line 35) and discloses introduction into a treatment bath (column 5, lines 14-17) and subsequent drying (inherent upon removal thereof) and contouring (column 4, line 13). SUGIYAMA et al [432] fails to disclose continuous introduction of a support into a housing wherein a blend is applied at a speed of 1 ft/min. GUNNING [044] teaches a well known continuous method of dipcoating a film (see figures 1 and 3-4), and further teaches the adjustment of film speed for the achievement of a particular film thickness (column 4, lines 12-27). It would have been well within the skill of the routineer of the art to continuously produce a membrane incorporating known continuous film coating process as taught by GUNNING [044] in combination with the process steps taught by SUGIYAMA et al [432] for the purpose of achieving economic benefits owing to the use of a continuous versus a batch production process.

Claims 1-39 have industrial applicability under PCT Article 33(4) because the subject matter claimed can be made or used in the blood separations industry.

---------- NEW CITATIONS ----------

US 5,700,902 A (HANCOCK et al) 23 December 1997, see column 5, lines 3-4 and column 15.
US 4,384,954 A (NAKASHIMA et al) 24 May 1983, see columns 3-4.
US 4,011,871 A (TAFT) 15 March 1977, see column 5, lines 40-47.